OPP-2002-0281

CropLife ☆AMERICA☆

June 16, 2003

SPP

JUN 16 2003

Public Information and Records Integrity Branch (PIRIB)
Office of Pesticide Programs (OPP)
Environmental Protection Agency (7502C)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

RE: NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities

Attention: Docket Identification Number OPP-2002-0281

CropLife America (CLA) submits these comments in response to EPA's request for comments on NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities (68 Federal Register 18638, April 16, 2003). CLA is a nonprofit trade association representing companies who manufacture, formulate and distribute crop protection products used in U.S. agricultural production. We are vitally interested in this Document because of the importance to our member companies not only as potential petitioners for NAFTA import tolerances, but also their interests and support of greater harmonization of NAFTA registration processes and the mutual acceptance of Maximum Residue Limits (MRLs) and import tolerances. The lack of globally harmonized MRLs and import tolerances is presently causing considerable uncertainty in food commodity export markets, making it difficult for producers and marketers to plan production and commit commodities for shipment. We continue to encourage EPA as part of the NAFTA Technical Working Group (NAFTA TWG) to make mutual acceptance of MRLs and import tolerances a reality within NAFTA and a precedent for advancing global harmonization.

CLA's comments to PMRA (April 10, 2003) recognized Canada's intentions to revoke its 0.01 ppm default MRL as an important opportunity for reaching critical endpoints in harmonization among the NAFTA countries. We encouraged PMRA to take every effort to ensure that trade irritants are not created from revoking the default MRL, results that would be consistent with the stated objective of the NAFTA Agreement, Article 102, to:

> "**Eliminate** barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties;"

Our overall reaction to the NAFTA Guidance Document is one of disappointment. We hoped it would advance clear guidance towards a harmonized approach for establishing NAFTA import tolerances. In reality, it is no more than a summary of the individual data requirements and submission formats of each NAFTA country. The Document states that specific data requirements of each country must be fulfilled and that petitioners must also adhere to their individual dossier formatting requirements. This means that three separate petitions will be required in hopes of obtaining one NAFTA import tolerance. Without a doubt, the Document misses an opportunity for advancing a harmonized approach for NAFTA import tolerances.

CLA supported EPA's proposed Guidance on Pesticide Import Tolerances and Residue Data for Imported Food (65 Federal Register 35069, June 1, 2000) on the basis that it provided a sound regulatory framework and a logical basis for decisions to assure public safety and health by preventing unacceptable levels of pesticide chemical residues in or on imported foods. (See CLA's comments, previously the American Crop Protection Association, dated July 31, 2000.) We also supported EPA's stated intention that its import tolerance guidance would form a basis for NAFTA guidance. Unfortunately, it appears that this did not happen.

We believe that NAFTA guidance on import tolerances should be based on fundamental principles that foster mutual acceptance of MRLs and tolerances among the NAFTA partners that include: 1) a common set of data requirements for import tolerance assessments, i.e. those pesticide hazard properties relevant to dietary exposures; 2) agreed upon approach for determining the number of field trials that maximizes the use of existing data from exporting countries; and 3) single submission format acceptable to all three NAFTA countries. The only mention of harmonization by the NAFTA Document is from the perspective of pilot joint reviews by the NAFTA TWG.

The Objective in the NAFTA Document, page 1, states that:

> *"The purpose of this document is to provide detailed guidance on data requirements that meet the North American Free Trade Agreement (NAFTA) standards for the establishment of pesticide import tolerances or maximum residue levels (MRLs) in Canada, Mexico and the U.S. This document has been developed consistently with the goals of NAFTA. A common NAFTA approach to import tolerances will promote trade between North America and the rest of the world"*

CLA certainly agrees with the Objective statement of "promoting trade between North America and the rest of the world", and the stated purpose, i.e. "to provide detailed guidance on data requirement that meet the North American Free Trade Agreement (NAFTA) standards for the establishment of pesticide import tolerances and maximum residue levels (MRLs) in Canada, Mexico and the U.S." Unfortunately, the Document does not follow through towards achieving this objective and instead identifies separate requirements of each NAFTA country. It also implies that guidance, or standards,

already exist for establishing import tolerances between the three NAFTA countries and that the Document expands on those standards as guidance for establishing import tolerances for non-NAFTA countries. CLA is not aware of the referenced NAFTA standards for establishing import tolerances or MRLs. The Objective in the Document also states that "the common set of data requirements listed herein typically will result in a reduced data set and a more efficient and cost effective process for petitioners to obtain import tolerances for all of North America." Unfortunately, the Document then proceeds to state that specific data requirements for each country must be fulfilled and that the petitioner must adhere to specific dossier formatting requirements.

We question how viable NAFTA import tolerance guidance can be for non-NAFTA countries when guidance on a standardized approach for establishing import tolerances among the NAFTA countries themselves has yet to be developed and put in practice. The use of a common set of data requirements agreed upon by the NAFTA countries for establishing import tolerances is a fundamental step to harmonized NAFTA import tolerances. Also, the goal of work sharing that is so strongly embraced by the NAFTA TWG and the OECD Working Group on Pesticides has a very important role in promoting both mutual acceptance and resource efficiencies in the NAFTA import tolerance process. The benefits of work sharing, namely, not repeating the same review process in each country, do not seem to be an integral part of the import tolerance process addressed in the Document.

With respect to the NAFTA Document's apparent lack of consideration to resource burdens imposed on import tolerance petitioners, CLA believes that a greater emphasis should be placed on promoting resource efficiencies. The NAFTA Document acknowledges that differences in data requirements and submission formats exist between the three NAFTA countries and therefore states that "Specific tolerance/MRL petition requirements (i.e. formatting, etc.) for each country must be adhered to, and separate import tolerance/MRL petitions must be submitted to each of the three NAFTA countries."

This was not the case with EPA's proposed June 2000 EPA guidance on import tolerances which stressed the intent to keep resource demands regarding new data for establishing or reassessing import tolerances to what are necessary and justified. EPA identified that the need for additional data to support import tolerance petitions would most likely be limited to those situations where a high percentage of the commodity is imported, potentially resulting in significant dietary exposure. The Agency provided examples of screening information to consider in establishing or reassessing a tolerance of tolerance exemption in deciding if additional information or data are needed on imported foods, regardless of whether the data are supporting import tolerance of a domestic registration with a significant import component. The types of screening information identified were:

- What international tolerances or MRLs exist?
- Which countries export the commodity to the U.S.?
- Major seasonal variations in imports of the commodity.

- Percent of U.S. consumption which is imported.
- Percent of crop treated in the exporting countries.
- Significance of the food in the U.S. diet.
- Effects of processing on the residues.
- Available information on levels of residues found in sampled of imported food (based on FDA, USDA, or other monitoring data.)

CLA emphasizes the importance and supports fostering efficiencies in the use of resources in establishing NAFTA import tolerances. Obviously, the greatest potential for efficiency gains, for petitioners and regulatory authorities, is in the collection, submission and review of data for establishing import tolerances. Relative to data collection, we believe that the NAFTA partners should maximize the use of existing data and the standardization of residue zone maps. We refer EPA to the proposal by the NAFTA Industry Working Group to consolidate the number of field trials needed to support NAFTA MRL/import tolerances.

Field trials are conducted to determine the maximum residue that may be expected in or on a raw agricultural commodity as a result of legal use of the pesticide. What is most relevant to establishing import tolerances is the potential residue levels that are available for dietary consumption. Monitoring studies, in general, whether conducted by enforcement agencies in other parts of the world or market basket studies conducted by individual registrants, generally reach the same conclusion—that most foodstuffs have no detectable residues. We believe that these data should be examined and utilized to the maximum extent feasible for determining the need for new field trial data from exporting countries. The use of these data should also allow the NAFTA TWG to target those import data requirements that are likely to affect the dietary risk assessments for each NAFTA country, and thus minimize the use of resources in areas unlikely to have any effect on the safety of the food supply.

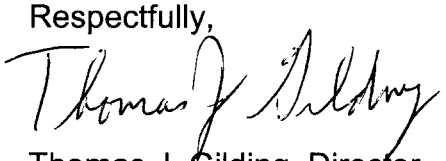
EPA OPPTS guidelines establish the minimum requirements for field trials needed in support of a submission for a tolerance and obtaining a registered use in the U.S. These requirements, relating to the number and location of field trials, serve as the basis in the NAFTA Document for determining the number of trials needed to establish NAFTA import tolerances. CLA believes that these requirements to be excessive and unnecessary for import tolerances. We do not believe the number of field trials with specified application rates, pre-harvest intervals, etc. for NAFTA import tolerances should be the same as if the NAFTA countries were establishing a registered domestic use. In other words, if a registered domestic use is not proposed, does the submission for an import tolerance need to meet the same guideline requirements?

The requirement that all field trials have the same rates, timings, pre-harvest intervals, etc. to qualify for joint reviews also needs to be reconsidered. Canada currently requires the submission of efficacy data granting registered uses. Canada also requires that residue trials have the same rates, timings, etc. as the efficacy trials. CLA understands that this combination can and has created problems with past joint reviews where trials from both the U.S. and Canada were included. A pesticide used in both the

U.S. and Canada may require slightly different application instructions, i.e. labels, due to factors such as pest pressure and differences in agronomic conditions. In the U.S., field trials from different parts of the country have the same application regime because residue levels, not efficacy, are the sole purpose of the trials. EPA labels give the proper directions for use, however the maximum rate, minimum pre-harvest intervals, etc. are not necessarily related to efficacy. That is why in the U.S. we can have a single protocol cover field trials from Florida to Washington. Although the NAFTA Document does not address efficacy, per se, the potential for field trial submissions with different application regiments exists especially if multiple countries are involved.

Please direct any questions or request for additional information concerning these comments to me at (202) 872-3873.

Respectfully,



Thomas J. Gilding, Director
Environmental Affairs